TPS4620 **Poster Session**

A randomized phase 2 study of the efficacy and safety of stereotactic body radiation therapy (SBRT) in patients with metastatic urothelial carcinoma and oligoprogression on maintenance therapy with avelumab (VOLGA 2).

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Background: For metastatic urothelial cancer (mUC) with multiple metastases, the standard treatment involves platinum-based chemotherapy followed by maintenance avelumab. Despite this, disease progression occurs in approximately half of patients at a median of 5.5 months, often requiring a switch to second-line therapy. The concept of oligoprogressive mUC and its optimal management remain poorly defined compared to other tumor types. The VOLGA 2 study aims to assess the preliminary efficacy and safety of SBRT in patients with mUC and oligoprogression during maintenance therapy with avelumab. **Methods:** VOLGA 2 is a randomized, prospective, multicenter phase 2 trial. Patients with histologically confirmed mUC and measurable lesions according to RECIST 1.1, undergoing avelumab maintenance therapy with extracranial oligoprogression, are randomized to receive SBRT targeting oligoprogressive lesions or to second-line therapy of the physician's choice. Oligoprogression is defined as disease progression due to the appearance of up to five new metastases or a significant increase in up to five existing lesions, with other disease sites remaining stable under ongoing systemic or local therapy. For patients in the SBRT arm, repeat SBRT to previously non-irradiated lesions is allowed and recommended if the interval between progressions exceeds four months. Patients with brain metastases and cord compression are excluded from the study. The primary endpoint is 2-year overall survival (OS) rate. Secondary endpoints include median OS and progression-free survival, overall and irradiated lesion response rates, and safety. The study will enroll 58 patients (H0 = 45%, Ha = 80%, alpha = 0.05, power = 0.8). Clinical trial information: KCRB10122024. Research Sponsor: Bureau for Cancer Research - BUCARE.